US ERA ARCHIVE DOCUMENT

Note to PM 03 Ann Sibold

Subject:

EPA Registration No 64240-33 Bracketing of CRP Test Data (DP Barcode

D259963)

The September 14, 1999 letter from Clorox discusses the bracketing of CRP test data based on an August 25, 1999 conversation between Evelyn Lawson and David Crawford, Clorox and myself. I agreed to some bracketing of CRP test data under two circumstances provided a number of conditions are met. The two situations are:

- When product toxicity is such that according to the CRP regulations¹ the child must access at least nine bait stations for a failure, a test using 12 bait stations would also cover any number of bait stations less than 12 bait stations. For example a 12 bait station test would also cover a 6 bait station retail package.
- When CRP protocol test data has been submitted, reviewed, and found acceptable for a series of bait station retail packages (e.g. 12, 18, 24, 72 bait stations) bracketing is possible for sizes in between those tested.

The conditions that must be met for permissible bracketing are as follows:

- A written submission indicating the test package sizes tested and the acceptable studies for these sizes along with an indication of the sizes in between being certified to CRP on the basis of these studies. EPA would have to approve any bracket sequence and the sizes not to be tested.
- The package being certified for CRP by bracketing must be identical to the two test packages in terms of debossing namely, all three packages must have the same debossing.
- The package being certified for CRP by bracketing must be identical to the two test packages in terms of film thickness, weld/seal, station size, % recycled plastic, holes for insects, tools sold with product, bait formulation properties concerning crumbling, fluidity, etc. The written submission for bracketing should clearly state that all these conditions have been met.

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¹ 16 CFR 1700.20 "a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower"